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IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, **v.** **ROB BONTA, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF CALIFORNIA,** Defendant.	2:20-cv-01708-TLN-DB **DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO MODIFY THE PRELIMINARY INJUNCTION** Date: February 10, 2022 Time: 2 p.m. Courtroom: 2 Judge: The Honorable Troy L. Nunley Action Filed: August 25, 2020

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INTRODUCTION

Defendant Rob Bonta, in his official capacity as the Attorney General of California (the "Attorney General") respectfully requests that the Court modify the preliminary injunction. As it currently stands, the injunction prohibits conduct that is undeniably constitutional, and in some cases, conduct that has not even been challenged by the Plaintiff. This action concerns Assembly Bill 824 ("AB 824") which provides that certain types of patent settlement agreements are presumptively anti-competitive under California antitrust law. Plaintiff Association for Accessible Medicines ("AAM") has brought a narrow, pre-enforcement dormant Commerce Clause challenge, asserting that "AB 824 violates the Commerce Clause *as applied* to settlement agreements that were not negotiated, completed, or entered in California." Dkt. No. 1 (Compl.) at ¶ 85 (emphasis added). The Court recently agreed, in part, with AAM's assertions and entered a preliminary injunction "enjoin[ing] enforcement of AB 824" under *any* circumstances. Dkt. No. 42 (Order) at 18.

This is a step too far: AAM has only challenged the extraterritorial application of AB 824 and has never alleged that the dormant Commerce Clause prohibits the Attorney General from enforcing AB 824 with respect to conduct occurring within California's own borders. The Court based its injunction on the premise that AB 824 may reach settlements where "none of the parties, the agreement, or the pharmaceutical sales have any connection with California." Order at 15. By enjoining enforcement of AB 824 under *any* circumstances, the Order reaches at least two scenarios not tethered to AAM's claims or the Court's reasoning: patent settlement agreements directly connected to pharmaceutical sales in California and settlements negotiated, completed, or entered in California.

An injunction must be drawn narrowly to fit only the conduct at issue. Because the injunction sweeps in conduct that is indisputably not a violation of the dormant Commerce Clause, the Court should modify the injunction to permit AB 824's in-state application and only prohibit the Attorney General from enforcing AB 824 against settlements with no connection to California.

RELEVANT BACKGROUND

AB 824 governs so called "pay-for-delay" agreements: patent litigation settlements whereby a branded pharmaceutical company pays a generic manufacturer not to offer a competing product for a certain amount of time. Order at 2-3. Under AB 824, a pay-for-delay agreement is presumptively anti-competitive under California antitrust law. *Id.* However, AB 824 does *not* reach all pay-for-delay settlements. It only applies to those made "in connection with the sale of a pharmaceutical product" in California. Cal. Health & Saf. Code § 134002(a)(1). Accordingly, if manufacturers want to avoid application of AB 824 to agreements they enter into, they can do so simply by omitting California sales from those covered by the agreement. *Id.*

AAM's primary claim is that AB 824 violates the dormant Commerce Clause as-applied to agreements that have no connection to California. *See* Compl. at ¶ 85 ("AB 824 violates the Commerce Clause as applied to settlement agreements that were not negotiated, completed, or entered in California"); *see also* Order at 8.[1] AAM does *not* bring a facial dormant Commerce Clause challenge. *See* Compl. at ¶¶ 79-85.

On September 14, 2020, AAM filed a motion for a preliminary injunction. As part of its motion, AAM reiterated that it was only bringing a pre-enforcement, as-applied challenge. *See, e.g.,* Dkt. No. 15-1 (Mot.) at 8 ("enforcing AB 824 against out-of-state settlements would constitute direct regulation in violation of the dormant Commerce Clause"). In his opposition, the Attorney General noted that "if AAM were asserting a 'facial challenge under the dormant Commerce Clause, [AAM] must establish that *no set of circumstances* exists under which the [AB 824] would be valid.'" Dkt. No. 20 (Opp'n.) at 7 n. 9 (quoting *Rosenblatt v. City of Santa Monica*, 940 F.3d 439, 444 (9th Cir. 2019) (emphasis added in opposition)); *id.* at 7 (referring to "AAM's pre-enforcement, as applied dormant commerce clause claim"). Given this, the fact that AB 824 might be unconstitutional in *some* instances is insufficient to enjoin it under *all* instances. Opp'n at 12 n. 15 (citing *Sabri v. United States*, 541 U.S. 600, 609-10 (2004) (overbreadth

[1] AAM has asserted other claims in its complaint. Because the Court did not reach those claims in its Order, they are not discussed here.

challenges arise in "relatively few settings" which derive from substantive First Amendment law)).

On December 9, 2021, this Court granted AAM's motion for a preliminary injunction. The Court held that AAM demonstrated a likelihood of success on the merits of its dormant Commerce Clause claim and otherwise met the requirements for a preliminary injunction. Order at 18. The Court first concluded that "a review of the relevant sections of [AB 824] reveals no [] limitation to only California sales." *Id.* at 14. The Court reasoned that "AB 824 may reach the kind of settlement agreements proposed by [AAM]—an agreement in which none of the parties, the agreement, or the pharmaceutical sales have any connection with California." *Id.* at 15. In light of this, the Court prohibited the "enforcement of AB 824." Order at 18. Though AAM's complaint, its motion, and the Court's order focused solely on the possibility that AB 824 could theoretically be used beyond California's borders, the Order had no geographic limitations and effectively enjoined the Attorney General from taking *any* enforcement action under AB 824. Order at 18.

LEGAL STANDARD

A motion to modify an injunction is usually evaluated as a motion for reconsideration. Accordingly, a Court may modify an injunction to "correct clear error or prevent manifest injustice." *Jablonski Enters., Ltd. v. Nye Cnty*, 2017 WL 4248131, at *2 (D. Nev. Sep. 25, 2017); *see also* Fed. R. Civ. P. 59 (governing motions for reconsideration); *Smith v. Clark Cty. Sch. Dist.*, 727 F.3d 950, 955 (9th Cir. 2013) ("Clear error occurs when the reviewing court on the entire record is left with the definite and firm conviction that a mistake has been committed").

As an "extraordinary remedy," an injunction must "be no broader than necessary to provide full relief to the aggrieved party." *Free Speech Coalition, Inc. v. Attorney General of the U.S.*, 974 F.3d 408, 430 (9th Cir. 2020) (district court abused its discretion in entering an overbroad injunction); *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1140 (9th Cir. 2009) ("[B]ecause '[i]njunctive relief must be tailored to remedy the specific harm alleged, [citation] an overbroad injunction is an abuse of discretion.'"). When a plaintiff asserts that a law is unconstitutional, a court should therefore "enjoin only the unconstitutional applications of a statute while leaving

other applications in force." *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 328-29 (2006) (where "only a few applications of [the challenged statute] would present a constitutional problem," lower court erred by enjoining the law in its entirety); *see also California v. Azar*, 911 F.3d 558, 582 (9th Cir. 2018) (partially voiding injunction which was broader than "*necessary* to give the parties the relief to which they are entitled" (emphasis in original)). In short, a court commits clear error if it issues a broad injunction against any enforcement of a statute where the plaintiffs have only brought a narrow, as-applied challenge. *Stormans*, 586 F. 3d at 1140 ("By enjoining enforcement of the rules, the district court erroneously treated the as-applied challenge brought in this case as a facial challenge").

ARGUMENT

The Court should modify the injunction to allow for AB 824's in-state application. There are at least two specific examples where AB 824 may be constitutionally applied consistent with the Court's Order. *First*, allowing AB 824 to be enforced whenever the relevant settlement is connected to pharmaceutical sales in California would not run afoul of the Court's concerns regarding settlements that lack "any connection to California." Order at 15. *Second*, AAM has never alleged that the dormant Commerce Clause prohibits California from enforcing settlements negotiated, completed, or entered in California.

In-state sales. It is well established that California's antitrust laws may cover out-of-state conduct so long as the relevant agreement or transaction impacts competition within California's borders. *Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979, 985, 994 (9th Cir. 2000) (where price fixing conspiracy in Wisconsin resulted in artificially decreased prices in California, the dormant Commerce Clause did not bar claims premised on California antitrust law); *Edwards v. Nat'l Milk Producers Federation*, 2014 WL 4643639, at *7 (N.D. Cal. Sep. 16, 2014) ("the commerce clause does not bar application of California antitrust law to out-of-state anticompetitive conduct that causes injury in California") (quoting *RLH Indus., Inc. v. SBC Commc'ns, Inc.*, 133 Cal. App. 4th 1277, 1281-82 (2005)).[2] Consistent with this basic principle

[2] *See also Brand Name Prescription Drugs*, 123 F.3d 599, 613 (7th Cir. 1997) (Alabama antitrust law could reach out of state conspiracies where the conduct ultimately impacted sales made in

of antitrust law, AB 824 may reach settlement agreements—even those negotiated, completed, or entered entirely out of state—if that agreement artificially distorts the pharmaceutical market in California.

This Court reasoned that AAM was likely to succeed because "AB 824 may reach . . . an agreement in which none of the parties, the agreement, or the pharmaceutical sales have any connection with California." Order at 14-15. But the Court's injunction was not limited to this scenario, and as currently constituted, prohibits California from enforcing AB 824 even when the relevant agreement is directly connected to pharmaceutical sales in California. Order at 18. The dormant Commerce Clause clearly permits such an action. *Edwards*, 2014 WL 4643639, at *7 ("the commerce clause does not bar application of California antitrust law to out-of-state anticompetitive conduct that causes injury in California"). Since "only a few applications of [AB 824] would present a constitutional problem"; the Court should not have prohibited California from enforcing the statute in all instances, but instead should "enjoin only the unconstitutional applications of a statute while leaving other applications in force." *Ayotte*, 546 U.S. at 328-29. The Court should accordingly modify the injunction to allow California to enforce AB 824 whenever the relevant agreement is made in connection with in-state pharmaceutical sales.

Furthermore, allowing California to continue to enforce AB 824 where there is a connection to California sales is consistent with the cannons of statutory interpretation. Under Californian constitutional law, California's statutes are presumed to only apply in-state. *RLH Indus*, 133 Cal. App. 4th at 1292 ("'California law embodies a presumption against the extraterritorial application of its statutes'").[3] And it is axiomatic that when a statute is subject to a constitutional interpretation, a court must adopt it if the alternative is striking down the law. *Rosenblatt v. City of Santa Monica*, 940 F.3d 439, 447 (9th Cir. 2019) ("Federal courts must accept a narrowing construction to uphold the constitutionality of an ordinance if its language is readily susceptible to

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Alabama; *In re Lorazapam,* 295 F. Supp. 3d 30, 48 (D.D.C. 2003) (dormant Commerce Clause permitted Illinois antitrust law to "extend[] not only to illegal antitrust activity that occurs wholly within Illinois, but also to activity which may have effects in that state and which may have occurred, in part, outside of Illinois.").

[3] The Court must apply California's cannons of statutory construction when interpreting California law. *In re First T.D. & Invs., Inc.*, 253 F.3d 520, 527 (9th Cir. 2001).

it") (quotation marks omitted). AB 824 only targets agreements made "in connection with the sale of a pharmaceutical product." Cal. Health & Safety Code § 134002(a)(1). The cannons of statutory interpretation accordingly presume that the California legislature only intended this law to apply to California sales. Allowing California to pursue an AB 824 enforcement action with respect to pharmaceutical sales in California would not run afoul of the Court's concerns regarding extraterritoriality, and would harmonize the injunction with this law.

Modifying the injunction in this manner would also be consistent with Ninth Circuit's dormant Commerce Clause precedent. In *Chinatown Neighborhood Ass'n v. Harris*, a group of plaintiffs challenged California's ban on the sale of shark fins, claiming it regulated commerce beyond California's borders. 794 F.3d 1136, 1145-46 (9th Cir. 2015). The underlying, challenged statute contained no express limitations to California, saying only that "it shall be unlawful for any person to possess, sell, offer for sale, trade, or distribute a shark fin." Cal. Fish & Game Code § 2021(b). Nevertheless, the Ninth Circuit presumed that the law would only apply to sales or possession "in California." *Chinatown Neighborhood Ass'n*, 794 F.3d at 1140. The Court went on to hold that while the law might have significant effects on out-of-state commerce, the fact that the law directly regulated sales in California meant that it did not violate the dormant Commerce Clause. *Id.* at 1146 ("nothing about the extraterritorial reach of the Shark Fin Law renders it per se invalid"). Here too, the Court should—consistent with California cannons of construction—presume that AB 824 only reaches California sales, and limit its injunction to enforcement actions with no connection to commerce within the state.

In state settlements. The injunction is especially overbroad given that AAM has effectively conceded that AB 824 *can* be constitutionally applied. AAM has explicitly limited its dormant Commerce Clause challenge to a single scenario: patent settlements completed entirely outside of California's borders. *See, e.g.,* Compl. ¶ 85 ("AB 824 violates the Commerce Clause as applied to settlement agreements that were not negotiated, completed, or entered in California"); Mot. at 7-8 (discussing AB 824's hypothetical application to "out of state settlements"). AAM has never argued that applying AB 824 to a settlement negotiated, completed, or entered *within* California's borders would run afoul of the dormant Commerce

Clause. Accordingly, at a minimum, the Court should modify its injunction to "enjoin only the unconstitutional applications of a statute while leaving other applications in force." *Ayotte*, 546 U.S. at 328-29; *see also Tielman Food Equip. BV v. Stork Gamco, Inc.*, 1995 WL 453392, at *2 (Fed. Cir., June 5 1995) (global injunction against patent infringer was overbroad and had to be limited only to U.S. territory).

REQUEST FOR CLARIFICATION

Separately, the Attorney General respectfully requests that the Court clarify and confirm that the injunction is only applicable as to AAM. AAM only moved to enjoin enforcement of AB 824 against "AAM, its member companies, or their agents and licensees." Dkt. No. 15. However, the Court's order did not contain any specific limitation to AAM, and instead "enjoin[ed] enforcement of AB 824." Order at 18. Consistent with the general rule that a plaintiff in an as-applied challenge may not obtain injunctive relief for third parties (*Free Speech Coalition*, 974 F.3d 408 at 430), the Attorney General respectfully requests that the Court confirm that the injunction only limits enforcement of AB 824 against AAM.

CONCLUSION

The Court should modify the injunction to only prohibit AB 824 from being enforced against agreements with no connection to California.

Dated: January 6, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

Case Name: **AAM v. Becerra** No. **2:20-cv-01708-TLN-DB**

I hereby certify that on January 6, 2022, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

DEFENDANT'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO MODIFY THE PRELIMINARY INJUNCTION

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California and the United States of America the foregoing is true and correct and that this declaration was executed on January 6, 2022, at Los Angeles, California.

Naomi R. Bolivar	/s/ Naomi Bolivar
Declarant	Signature

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